



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/490,064 01/24/00 KNAPPIK

A 047744/0107

HM12/0710
HELLER, EHRMAN, WHITE & MCAULIFFE
815 CONNECTICUT AVENUE
SUITE 200
WASHINGTON DC 20006

EXAMINER

ZEMAN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

07/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/490,064

Applicant(s)

KNAPPIK ET AL.

Examiner

Mary Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 56-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/025,769.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

The preliminary amendment filed with the application has been entered. This amendment canceled claims 1-55 and adds claims 56-63.

Applicant's attorney of record for the previous application (P. Booth) indicated in an interview in May, 2001 that new claims would be submitted shortly which would reflect the claims allowed in the Parent Application 09/025769. As of the date of this communication, no additional claims had been submitted in this application.

The amendment filed 9/15/00 could not be entered into the specification. The pages and line numbers are different. For example, Page 5, line 5 has no recitation of "(A)" such that any sequence identifier could be entered. This line begins: "database of the protein sequences is established..." Applicant is requested to resubmit the amendment changed to reflect proper page and line numbers so that the application complies with the sequences rules, as required. Failure to provide such amendments will render the reply non-responsive.

Priority

This application is a divisional application of a US 371 application 09/025769. This divisional, filed as a US case, has the same specification on file with the International Bureau, including substitute pages according to PCT Rule 26, but does not have other changes which may have been made in the prosecution of the International application, or the 09/025769 application.

Priority to PCT/EP96/03647 filed 19 August 1996, and EP 95113021.0 filed 18 August 1995 is acknowledged.

Claim Rejections - 35 USC § 112

Claims 57, 59, 61 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims refer to a "collection of vectors" in reference to claim 56. Claim 56 recites a single vector, not multiple vectors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 56-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al. (US Patent 5,693,493).

The claims are drawn to nucleic acids encoding polypeptides having consensus sequences which are modular in nature, allowing switching of particular domains at will, due to the virtue that the domains are flanked by particular restriction sites.

Robinson et al. (US Patent 5,693,493, with priority under 35 USC 120 to 1990) disclose methods of preparing polynucleotide sequences which encode human immunoglobulin sequences (see for example, the abstract). Immunoglobulins are a family of polypeptides which have known consensus sequences for particular portions. Each domain of the immunoglobulin sequence is modular in nature (column 13 lines 66-67), and flanked by particular, unique restriction sites (see for example, the legends of figures 7 and 12, column 27 lines 40-55, the examples etc.). A variety of CDR sequences to a variety of antigens can be cloned into the framework sequence to provide a polynucleotide sequence encoding an immunoglobulin with a particular binding specificity (represented by Example III). The engineered sequences can be cloned into vectors for expression in eukaryotic or prokaryotic host cells for expression of the encoded polypeptides. Kits comprising those vectors are contemplated by Robinson.

Claims 56-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Queen et al. (US Patent 5,693,761).

Queen et al. (US Patent 5,693,761, having priority under 35 USC 120 to 1988) disclose methods of preparing polynucleotides comprising humanized immunoglobulin sequences, which include one or more CDR regions, and four framework (consensus) regions and a variety of CDR regions can be cloned into the humanized framework. (see, for example, the abstract). The amino

Art Unit: 1631

acid sequences are compared to consensus sequences for the various domains (col 13 lines 6-64, col 15 lines 47-50, col 17, lines 15-30), and adjusted to promote the best folding, and most stable encoded polypeptides. The nucleic acid sequences were also optimized to add restriction sites (column 44 lines 56-57), and to adjust for codon bias (column 44 lines 55-56). Example 3, at columns 43-45 specifically disclose the design of the humanized antibodies, including the optimization of the polypeptide and polynucleotide sequences. The polynucleotide sequences encoding the immunoglobulin sequences were cloned into appropriate vectors for recombinant expression. Kits comprising the expressed vectors are contemplated by Queen.

Conclusion

No claim is allowed.

Copies of Queen et al. and Robinson et al. are not provided as they are of record in the parent application, 09/025,769.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The official fax number for this Art Unit is (703) 308-4242. An unofficial fax number, direct to the Examiner is 703 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz
6/29/01


MARY K. ZEMAN
PATENT EXAMINER
